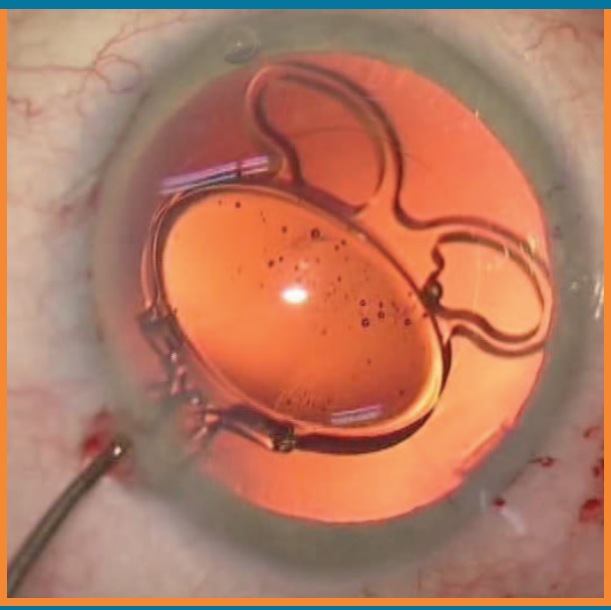
Insert to October 2009

Cataract & Refractive Surgery TODAY EUROPE

Microincisional IOLs

Living Up to Expectations



INSIDE:

PRODUCED UNDER AN EDUCATIONAL GRANT FROM PHYSIOL

Why Use a Hydrophilic Acrylic IOL in 2009?

Security, reliability, and adaptability to microincisions.

BY GILLES LESIEUR, MD

Biaxial and coaxial microincisional cataract surgery are not currently accepted by most cataract surgeons because of the learning curve these techniques require[1] and the previous unavailability of implants that meet the modern surgical standards of stability and the prevention of posterior capsular opacification (PCO). However, we now have lens implants that can pass through incisions smaller than 2 mm and that are made of hydrophilic acrylic, a material for which the quality has been proven in the 21st century. (IOLs made of hydrophobic acrylic materials cannot currently be injected through incisions smaller than 2.2 mm.)

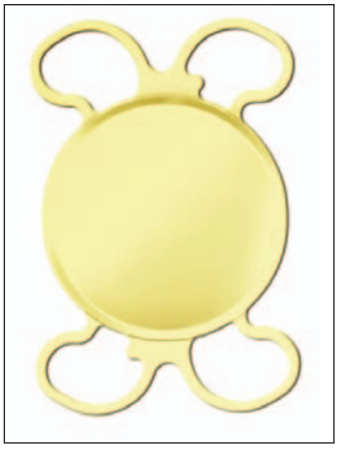


Figure 1. The hydrophilic acrylic Micro AY IOL.

The first hydrophilic IOLs, designed in the 1990s, were made of pure HEMA (38% water content) and were too easily deformed. Today, manufacturers have developed more stable IOLs out of copolymers of HEMA and PMMA.[2] The most stable implants are made of 25% (HEMA-co-EMA) and 26% (HEMA-co-MMA) water content.

EXPECTATIONS FOR IOLs

Beyond the debate on incision size (which will cease once all cataract surgeons adopt the biaxial technique, thanks to the availability of IOLs that can pass through sub–1.5-mm incisions, as demonstrated by the development of vitreoretinal surgery), the question is, what do we expect from an IOL?

- stability
- PCO prevention
- spherical, toric, and/or multifocal correction
- reduction of spherical aberrations and customization
- retinal protection with UV and blue-light filters
- short- and long-term transparency of the lens' optic without deposits or glistenings

Stability

In order for an IOL to be suitable for the most frequently performed surgery in the world, its stability must be irreproachable. It must be able to adapt to the capsular bag's contraction, which culminates at 3 months. Numerous articles have reported on the instability of plate haptics after an Nd:YAG laser capsulotomy with IOLs made of silicone materials that are no longer used.[3] In my experience, plate-haptic IOLs do not show more instability or opacification than the three-piece designs recommended by some surgeons.

Other IOL designs featuring four haptic fixation points, such as the Micro AY (PhysIOL; Liège, Belgium; Figure 1) or Akreos MI-60 (Bausch & Lomb, Rochester, New York), are compatible with microincisions and have demonstrated their stability in the capsular bag.[4] This design eliminates the compromise between modern surgical standards and sub–2-mm incisions. Four-haptic IOLs have an optical zone that is usually 6 mm in diameter (6.15 mm for the Micro AY and 5.6 to 6.2 mm for the MI60), their posterior angulation is 5° to 10°, and they have a 360° posterior square edge.

PCO

The latest generation of IOLs effectively inhibits PCO. A study I conducted on 699 implants of the MicroSlim and Micro AY IOLs (PhysIOL) showed a 1.22% rate of Nd:YAG capsulotomies at 1 year[4] and 5.42% at 3 years (Figure 2). Furthermore, various studies have confirmed that an IOL's design[5] is much more important than its material in reducing PCO.[6] The risk of capsular opacification is greatest at the optic-haptic junction, as shown in a study comparing the AcrySof three-piece and single-piece IOLs (Alcon Laboratories, Inc., Fort Worth, Texas). The investigators found less efficacy of the anti-PCO barrier

with the single-piece lens, although the two were made of the same hydrophobic acrylic material.[7]

Asphericity, Astigmatism, and UV Protection

Companies have developed hydrophilic acrylic IOLs with aspheric optics that more or less compensate for corneal spherical aberrations. Clinical results seem to be similar between hydrophobic and hydrophilic designs.[8] One must also evaluate the clinical value of true customization to correct these spherical aberrations, considering that some amount of spherical aberration is needed to preserve depth of field. I personally target approximately +0.15 µm of spherical aberration.[9] The clinical benefit for cataract patients, who are mostly elderly and have limited scotopic pupil dilation, remains in question.

Astigmatism of less than 3.00 D, which previously was corrected with limbal relaxing incisions, may now be treated with hydrophilic and hydrophobic toric IOLs. Multifocal lenses are also available in both materials. In addition, IOLs of both materials are available with UV blockers and yellow chromophores. The combination of a blue-light filter with the hydrophilic material gives the Micro AY lens better compressibility and greatly facilitates its injection through a 1.8-mm wound (final incision size). This compressibility and the benefits of a blue-light filter for young patients are what I consider to be the main advantages of this chromophore.

Clarity

I believe optical transparency is the most important factor in IOL design. Opacifications have been documented for both hydrophilic and hydrophobic acrylic lenses.[10-12] First-generation hydrophilic IOLs have shown calcification[13] due to a lack of control over the polymerization process (residual monomer, anti-UV agent, methacrylic acid, and a low density of the reticulated network) and/or components of the IOL's packaging. Hydrophobic IOLs, which have a water uptake at equilibrium of less than 5%, also present a risk of opacification through a phenomenon known as *glistening*, which is caused by intraocular temperature variations (ie, a cycle of rising then decreasing temperatures).[14] Water vapor condenses inside the lens and forms droplets. The phase separation between the water droplets and the lens polymer creates vacuoles.[2] All current hydrophobic materials are likely to develop glistenings, which in certain cases may completely opacify the lens and lead to its explantation.[12] Hydrophobic IOLs manufactured by machining rather than molding (the most widely used process) are less susceptible to glistening.[2]

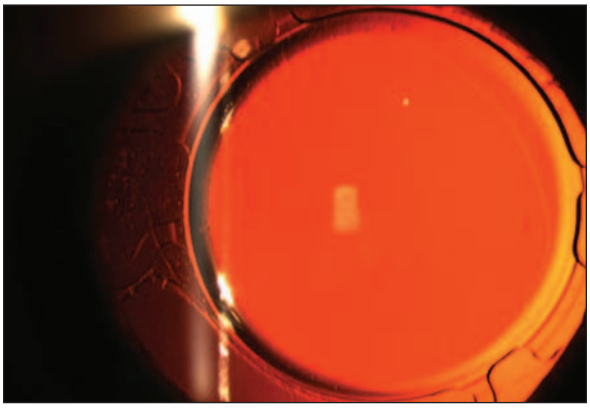


Figure 2. A clear posterior capsule 18 months after implantation of the Micro AY IOL.

SUMMARY

Today's various arguments against hydrophilic IOLs are unfounded and refer to lenses of the last century. In contrast, the latest generation of implants offers security, reliability, and adaptability to microincisions. Surgeons need no longer compromise to use microincisional IOLs. Moreover, the development of new IOL injection systems will further push the current limits of the incision's size before the development of new polymers that will fill the capsular bag and restore accommodation … if we are able to control PCO.[11] ■

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The 1.2.3. Injection Systems

A simple, safe, and efficient way to deliver preloaded IOLs.

BY PIERRE-YVES SANTIAGO, MD

The new ability to use microincisions in cataract surgery has revolutionized ophthalmic phacoemulsification and IOL implantation. This article focuses on the use of preloaded injection systems to implant microincisional IOLs.

SUCCESSFUL DESIGN

Flexible optic materials represented the first major step in enabling IOLs to pass through microincisions. For years, surgeons had to fold lens implants using various devices that required manual manipulation, which increased the risk of the lens' bacterial contamination prior to implantation. Thus, the introduction of hand-loaded IOL injection systems became the second milestone in microincisional surgery, once the manufacturers had perfected the materials and designs of the cartridges. Yet, bacterial contamination of the lens was still possible with these systems, because surgeons had to manually load the IOL into the cartridge. Therefore, preloaded IOL injection systems seem to be the safest solution for patients.

Although most IOL manufacturers have attempted to design a preloaded IOL injection system, only a few have been able to successfully balance the complexities of the task. The best IOL injection systems use a preloaded cartridge that is able to accommodate lenses made of the optimal hydrophilic acrylic IOL material and insert them through incisions of 1.8 to 2.2 mm. PhysIOL (Liège, Belgium) has a particularly ingenious system that allows the safe implantation of its 1.2.3. range of IOLs.

THE 1.2.3. INJECTION SYSTEMS

The 1.2.3. injection systems (the 1.2.3. System and the 1.2.3. Premium) consist of two parts. The first is a cartridge that is placed in a vial. The vial is filled with an isotonic saline bath and contains an IOL made of the company's proprietary hydrophilic material. The second part of the system is the disposable injector, of which the surgeon may choose from two designs: one that advances the IOL via a screwing motion, and one that advances the IOL via a plastic plunger. A silicone tip sits atop the plunger. Both injectors allow the surgeon to insert the IOL gradually and gently without damaging the IOL or the wound.

The 1.2.3. System injector is simple to use and eliminates the risk of septic contamination of the IOL. The surgeon simply clips the cartridge to the injector. He may lightly irrigate inside the cartridge with balanced salt solution to wash out the isotonic storage solution before placing a small quantity of viscoelastic inside the injector.

CLINICAL EXPERIENCE

In my experience, the 1.2.3. System injector implants the IOL quite smoothly. It passes the lens through a 2.8-mm incision easily and a 2.2-mm incision with little effort in routine clinical practice. For 2.2-mm incisions, I hold the injector at the entrance of the corneal tunnel and position the superior part of the cartridge's tip below the wound's superior edge. The pressure on the plunger must be firm and steady so it does not move; the eyeball itself supplies the counterpressure when it is blocked nasally (for a temporal clear corneal injection).

PhysIOL's R&D department has been refining the 1.2.3. System injector since 2003. The company launched its first preloaded lens, the SlimFlex-m 1.2.3., in May 2007, and then replaced it with the Slim AY 1.2.3. in May 2008. This 25% hydrophilic acrylic IOL features a 360° square edge with 5° angulation, which I have found particularly effective in preventing posterior capsular opacification.

I use the Slim AY 1.2.3. lens with the 1.2.3. System injector daily, and my patients are very happy with their outcomes. Most outcomes deviate less than 0.50 D from their preoperative targets. Complications during the lens' implantation (eg, incomplete injections with a portion of the lens remaining outside of the eye, a torn IOL, or damage to the corneal wound) are rare. I look forward to trying the newest 1.2.3. Premium system when it becomes available at the end of this year. This latest version will facilitate implantations through 2.2- and even 1.8-mm microincisions via a thinner cartridge tip. ■

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MICS and the Micro AY 1.2.3. IOL

The benefits and future of microincisional cataract surgery.

BY DANIELLE DEIDIER, MD

Cataract surgeons have an imperative to preserve the cornea's structural integrity during a procedure. Microincisional cataract surgery (MICS) fully meets this requirement. At the 2007 ESCRS meeting, I presented the results of a study in which I operated on 400 eyes with a bimanual cataract technique through a 1.3-mm incision (I enlarged the wound to 1.7 mm to implant the IOLs).[1] This study confirmed that the bimanual technique does not induce astigmatism. I used three types of IOLs bilaterally in three groups of patients: the Akreos MI-60 (Bausch & Lomb; Rochester, New York) (n=300), the MicroSlim (PhysIOL; Liège, Belgium) (n=50), and the Quatrix (Croma; Korneuburg, Austria) (n=50). Each group's preoperative astigmatism averaged 1.08, 0.88, and 0.67 µm, respectively. Table 1 shows the groups' postoperative astigmatism at 1 and 3 months after surgery. The axis of the astigmatism did not change in any eye. Endothelial cell loss was minimal: a mean of 170 cell/mm^2 for the Akreos MI-60, 222 cell/mm^2 for the MicroSlim, and 235 cell/mm^2 for the Quatrix.

I evaluated the long-term stability of these results and presented the findings at the 2009 ASCRS meeting.[2] The 2-year results on 52 of the eyes implanted with the MicroSlim showed that their BCVA was very stable: 0.92 at 1 month, 0.94 at 3 months, 0.93 at 6 months, 0.92 at 12 months, and 0.91 at 24 months. No eye required an Nd:YAG laser capsulotomy. Ninety percent of the posterior capsules were still clear at 2 years; only 6% had mild fibrosis, and 4% had moderate fibrosis. I hypothesized that the stability of the MicroSlim's four-point fixation, its 5° haptic angulation, and the uninterrupted square edge on the hydrophilic acrylic optic's periphery are all factors that contributed to the quality of these long-term results.

THE BIMANUAL CATARACT TECHNIQUE

Intraoperatively, the bimanual technique presents numerous advantages. It minimizes intracameral movements, provides more control over complications, and it allows for combined surgeries such as a nonpenetrating sclerectomy. Furthermore, the bimanual technique is fast with minimal trauma, and patients can return to their routine activities almost immediately.

TABLE 1. POSTOPERATIVE ASTIGMATISM (µm)

	Akreos MI-60 (n=300)	MicroSlim (n=52)	Quatrix (n=50)
1 Month	0.73	0.70	0.83
3 Months	0.83	0.65	0.70

LENS INSERTION

Soon, surgeons will have access to PhysIOL's new Micro AY 1.2.3. IOL, which has the same design as the MicroSlim IOL but features a blue-light blocker and an aspheric optic to correct corneal aberrations. The AY implant will come preloaded in the 1.2.3. Premium injector, which will eliminate the surgeon's contact with the lens. He or she will simply open the cartridge and click it into the injector. The dimensions of the injection cannula are similar to those of the company's MicroSet cartridge and should pass the lens easily through 1.7- to 1.8-mm incisions using a wound-assisted technique. I presented preliminary in vitro testing of the 1.2.3. Premium injector at the recent ASCRS meeting.[2] Since then, the design has been fine-tuned. The device's injection is smooth and linear, and the Micro AY lens unfolds gently in the eye. This new device will make lens injection through microincisions even safer and more reproducible. The company anticipates the 1.2.3. Premium injector to be available by the end of the year.

Bimanual MICS has benefitted from simplified surgical techniques and from new microincisional IOLs that offer stability and enhanced optical quality. I expect the new 1.2.3. Premium preloaded system for the Micro AY lens to decrease surgeons' micromanipulations and hence increase asepsis and intraoperative safety. ■

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IOL Centration and Stability

The advantages of four fixation points on a pseudophakic microincisional IOL.

BY CHRISTOPHE CHASSAIN, MD

Early hydrophilic acrylic IOLs with closed-loop haptics developed a bad reputation because of their high rates of secondary cataract versus hydrophobic acrylic IOLs with open loops. The incidence of cataract was attributed to the hydrophilic material's poor adherence to the posterior capsule and to the lack of an edge at the junction of the IOLs' haptics, which encouraged epithelial cells to migrate from the capsular bag's equator to the optic.

More recent hydrophilic acrylic IOLs such as the SlimFlex (PhysIOL, Liège, Belgium) have a ridge on the periphery of the posterior surface of their optic that does not interrupt the haptics' junction with the optic. At the 2007 SAFIR congress, I presented a study on 2-year Nd:YAG laser rates for 344 patients implanted with the SlimFlex IOL.[1] Eleven patients (3.21%) required Nd:YAG capsulotomies; results that are similar to 2-year Nd:YAG rates seen with the three-piece AcrySof IOL (Alcon Laboratories, Inc., Fort Worth, Texas) in 2004.[2]

The SlimFlex and its counterparts, the YellowFlex IOL (the first hydrophilic lens with a yellow chromophore) and the Micro AY (for microincisions) all have a 360° square edge and offer the same advantages as conventional IOLs with four-point fixation. The main benefit of these lenses' short haptics and four fixation points is immediate centration in the capsular bag. Their numerous haptic bridges reduce tilting and fibrosis at the optic's periphery by preventing optic capture by a capsulorrhexis that is too large or decentered. Because of their limited overall diameter, however, these IOLs cannot ensure rotational stability in large capsular bags and therefore cannot aspire to toric correction of astigmatism.

ASTIGMATIC CORRECTION

Astigmatic correction can be achieved with the new 26% hydrophilic Pod AY implant from PhysIOL. The lens' 11.17-mm design represents a compromise between the two main types of IOLs. Like C-loop lenses, it has two open haptics that will adapt to the diameter of most capsular bags; but similar to closed-loop lenses, it has four fixation points via two opposing branches on each haptic.

I implanted 113 eyes with the hydrophilic Pod AY IOL between October 2008 and March 2009. I evaluated the lens' behavior during injection, the possibility of intraoperative rotation, and its postoperative stability and rotation at 1 week, 3 weeks, and 3 months (Table 1).

TABLE 1. THREE-MONTH REFRACTIVE STABILITY WITH THE POD AY IOL

Week	1 (114 eyes)	3 (116 eyes)	15 (8-36) (111 eyes)
BCVA	0.95	0.95	0.98
*SE	-0.45	-0.45	-0.38
Rotation	-	0	0

* Myopic spherical equivalent due to the monovision technique used in most patients.

I injected the Pod AY through a 2.4-mm incision using a wound-assisted technique. I achieved autocentration quickly and was able to rotate the lens easily both clockwise and counterclockwise. I positioned the IOL so that one of its haptics faced the incision. The average BCVA and spherical equivalent were 0.95 and -0.45 D, respectively, at 1 week, 0.96 and -0.45 D at 3 weeks, and 0.97 and -0.43 D at 3 months. I observed no postoperative rotation of the lens, even in eyes with a very large capsular bag, where rotation of the lens was observed during the removal of the viscoelastic. To avoid this rotation, PhysIOL is developing an implant with an optic 11.40 mm in diameter, which is close to the size of the largest capsular bags measured to date.[3] This new IOL will be thinner, made of hydrophobic material, and injectable through incisions smaller than 2 mm. ■

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Photoprotection and Photoreception With Blue-Light–Filtering IOLs

The photosensory benefits for patients.

BY BABAK MASHHOUR, MD

The development of IOLs that filter UV light and attenuate wavelengths of between 400 and 500 nm has been the subject of interesting debate over the past 5 years. Several issues have been raised concerning the blue-light–filtering characteristics of IOLs, such as:

1. their photoprotective effect in damaged retinas (ie, those with a history of age-related macular degeneration (ARMD), macular surgery, diabetic retinopathy, etc.) or healthy but physiologically aging retinas;
2. their potential impact on retina-related neurosensory factors such as circadian rhythms, scotopic vision, and color perception in operated eyes compared with IOLs that only block UV light; and
3. whether they will alter retinal visualization.

This article attempts to briefly address these debates.

BLUE-LIGHT HAZARD AND PHOTOPROTECTION

A variety of hereditary and environmental factors are involved in the pathogenesis of ARMD. High-energy (blue) and UV-A radiation can induce photochemical light damage in aphakic or pseudophakic eyes. Blue-light–filtering IOLs have a putative prophylactic effect against blue radiation, particularly in ARMD eyes, because these lenses absorb not only blue light (430 nm) but also damaging green light (550 nm). Based on this theory, IOLs with such filters could limit the oxidative stress on the retinal pigment epithelial cells caused by free radical agents in all aging eyes and particularly those with ARMD. Antioxidant therapy combined with blue-light–filtering IOLs may counteract the degeneration of photoreceptor and retinal pigment epithelial cells in eyes with ARMD and prevent it in aging eyes.

PHOTOSENSORY IMPACT OF BLUE-LIGHT–FILTERING IOLs

Blue-light–filtering IOLs may affect different sensory factors, such as circadian rhythms, scotopic vision, or even color perception and contrast sensitivity.

Circadian Rhythms

Blue light ranges from 400 to 500 nm. Because the release and suppression of melatonin are highly complex, the filtering and even complete blockage of blue light alone would not significantly affect circadian functions. IOLs that do not filter the low-energy range of blue light in the longer wavelengths (480 to 510 nm) preserve sensory functions such as circadian regulatory mechanisms. Furthermore, blue-light–filtering lenses transmit more than 70% of 480-nm light, which is the same transmission as a child's natural crystalline lens. My colleagues and I conducted a prospective data analysis of more than 850 patients implanted bilaterally with blue-light–filtering IOLs in the past 2 years (unpublished data, 2009). We found no significant differences in the quality of these patients' sleep rhythms, and we therefore continue to use blue-light–filtering lenses (the Slim 1.2.3. and the Micro AY [PhysIOL; Liège, Belgium]) in our patients.

Scotopic Vision

Rod-mediated scotopic vision functions at approximately 507 nm and tends to decline physiologically with age. The potential causes of deterioration in scotopic vision are degeneration of the rods, media opacities (cataract), and impairment of the transduction pathways. Theories that blue-light–filtering IOLs compromise scotopic and mesopic vision should be reconsidered and tested by comparing the light transmission

through different lenses. A recent study comparing UV-blocking and blue-light–filtering IOLs found no significant differences in the performance of scotopic vision in natural lighting conditions between these two lenses.[1]

Another aspect of the blue-light–blocking controversy suggests that blue-light transmission should be enhanced to ensure the best possible scotopic vision. As mentioned previously, UV-only–absorbing IOLs offer no significant advantage over blue-light–filtering lenses in elderly patients with dysfunctional rods and deteriorating transduction.[1] In our series, patients with bilateral blue-light–filtering IOLs (the Slim 1.2.3. and the Micro AY) had no complaints in a wide range of lighting conditions, especially while driving at night or in low-light environments, compared with their preoperative quality of vision.

Color and Contrast Vision

Cone-mediated photopic vision is specialized in different wavelengths. By restoring patients' natural contrast vision, blue-light–filtering lenses improve contrast sensitivity in daylight. One study of patients who received a UV-filtering IOL in one eye and a blue-light–filtering IOL in their fellow eye found that contrast sensitivity was better in the latter eye and closely mirrored that of a healthy, age-matched control group.[2] Postoperative visual acuity and color perception were similar with both types of lenses, and these findings were confirmed in other studies.[3,4] Furthermore, a significant improvement in color discrimination was noted in the blue-yellow axis in a group of diabetic patients implanted with blue-light–filtering IOLs.[5]

These data reinforce the proposal that blue-light–filtering IOLs should be used in all patients at risk for acquired or hereditary macular disturbances.

Optical Access to the Retina

IOLs with blue-light filters gives surgeons excellent visualization of the retina in cases where retinal surgery is indicated. Postoperatively, macular pathologies do not seem to progress in patients implanted with these lenses. In a personal series of 245 consecutive patients who required macular surgery (for macular hole, macular pucker, or diabetic macular edema) combined with cataract surgery, I used either the Slim 1.2.3. or the Micro AY in all cases. Postoperatively, these lenses did not interfere with my visualization during dissection of the internal limiting membranes. ■

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